DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 22 1993

Re: ZEBETA®
Docket No. 92E-0427

#17

The Honorable Douglas B. Comer
Acting Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Comer:

This is in regard to the application for patent term extension for U.S. Patent No. 4,258,062, filed by E. Merck GmbH, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for ZEBETA®, the human drug product claimed by the patent.

The total length of the review period for ZEBETA® is 2,874 days. Of this time, 1,778 days occurred during the testing phase and 1,096 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: September 19, 1984.

   The applicant claims September 16, 1984, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 19, 1984, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: August 1, 1989.

   The applicant claims July 28, 1989, as the date the new drug application (NDA 19-982) was filed. However, FDA records indicate that NDA 19-982 was submitted on August 1, 1989.

3. The date the application was approved: July 31, 1992.

   FDA has verified the applicant's claim that NDA 19-982 was approved on July 31, 1992.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Harry B. Shubin
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